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10/540,405

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Eric E. Schadt

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EXAMINER

DEJONG, ERIC S

ART UNIT

PAPER NUMBER

1631

NOTIFICATION DATE

DELIVERY MODE

01/27/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efiling@cojk.com

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/540,405 | Applicant(s) SCHADT ET AL. | |
| | Examiner ERIC S. DEJONG | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 168-194 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 168-194 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Applicants response filed 10/23/2010 is acknowledged.

Election/Restrictions

Applicant's election without traverse of Group IV (claims 168-194) in the reply filed on 03/18/2010 is acknowledged.

Claims 1-167 and 195-202 are cancelled.

Claims 168-194 are currently pending and under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 168-194 are rejected under 35 U.S.C. 101 because .the claimed invention is directed to non-statutory subject matter. This rejection is maintained from the previous Office action.

In the instant case, each independent claim is directed to a method identifying a molecular target. The recited process comprises only abstract steps directed to identifying genes, mapping genes, and determining therefrom a specified relationship between naturally occurring genetic loci of a segregated population. The recited process steps involve establishing a series of abstract correlations that purport to identify a

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naturally occurring relationship between a specified gene and markers mapped to identifiable genetic loci. Such amounts only to an expression of an abstract thesis as the instant claims do not recite any positive limitation wherein physical steps or interactions occur. A practitioner of the instant need not perform any physical act nor would said practitioner be required to interact in any definitive physical object or specified apparatus in a particular manner.

It is further acknowledged that all independent claims have been amended to nor recite that at least one of the steps is performed by a suitably programmed computer. However, this newly recited limitation only tangentially suggests the involvement of a programmed computer in conjunction with the claimed processes. The amended claims in their current form do not specify what particular acts, computations or calculations the recited suitable programmed computer actually performs in order to accomplish the abstract process steps acts identified above process steps directed to identifying, mapping and determining naturally occurring correlations between generic genetic loci of a segregated population. As such, it is maintained that the instant claims lack both a tie to a particular machine or apparatus, nor do the involve any transformation of a particular article into a different state or thing. For these reasons, the claimed invention is directed to non statutory subject matter.

Claims 168-194 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. This rejection is maintained from the previous Office action.

In the instant case, each independent claim is directed to a method identifying a molecular target. The recited process comprises only abstract steps directed to identifying genes, mapping genes, and determining therefrom a specified relationship between naturally occurring genetic loci of a segregated population. The recited process steps involve establishing a series of abstract correlation that purport to identify a naturally occurring relationship between a specified gene and markers mapped to identifiable genetic loci. Such amounts only to an expression of an abstract thesis as the instant claims do not recite any positive limitation wherein physical steps or interactions occur..

However, the instant claims do not recite any particular improvement or resultant characteristic that is imparted to genes identified by the instant method or how analysis of the resultant sequences would be used to yield any useful information. The Court of Patent and Appeals has stated:

"Practical utility is a shorthand way of attributing "real-world" value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." A 'use' to do further research is not considered a utility which provides an "immediate benefit" to the public.

Examples of situations requiring further research to identify or reasonably confirm a "real world" context of use, and which do not have utility under 35 USC 101, as set forth in MPEP 2107.01.1, include:

(A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved', and

(C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility.

The instant claims encompass a process of basic research drawn to studying properties of a protein structure and as such do not result in an "immediate benefit" to the public. As noted in the utility guidelines (see Federal Register, December 21, 1999, Vol. 64, No. 244), basic research on a product to identify properties is an insubstantial utility

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(see page 6 of the Utility guideline training materials). Therefore, the instant claims do not have a substantial utility.

Claim Rejections - 35 USC § 112, Enablement

Claims 168-194 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to Arguments

Applicant's arguments filed 0/25/2010 have been fully considered but they are not persuasive.

In regards to the rejection of claims under 35 USC 101 as being directed to non-statutory subject matter, applicants argue that the instant claims have been amended to now recite the use of a suitably programmed computer.

In response, it is reiterated from the instant rejection that all independent claims have been amended to now recite that at least one of the steps is performed by a suitably programmed computer. However, this newly recited limitation only tangentially suggests the involvement of a programmed computer in conjunction with the claimed processes. The amended claims in their current form do not specify what particular acts, computations or calculations the recited suitable programmed computer actually

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performs in order to accomplish the abstract process steps acts identified above process steps directed to identifying, mapping and determining naturally occurring correlations between generic genetic loci of a segregated population. As such, it is maintained that the instant claims lack both a tie to a particular machine or apparatus, nor do the involve any transformation of a particular article into a different state or thing.

With regard to the rejection of claims under 35 USC 101 lacks patentable utility and the related rejection of claims under 35 USC 112, 1st paragraph, applicants argue that the identification of a molecular target for a second trait in a second species has a substantial application and, further, that one skilled in the art would recognize what these results mean (and thus how it can be used).

In response, it is noted that the utility requirement under 35 USC 101 is met by claims having a specific, substantial and credible utility. Applicants argument that the by practicing instantly claimed process one would arrive at the identification of a naturally occurring correlations for a molecular target to a second trait in a second species sufficient to establish that the instant claims have a specific and credible utility. However, the basis of the instant rejection is that the instant claims fail to meet the substantial utility prong of set forth in 35 USC 101.

It is emphasized from the above rejection that the Court of Patent and Appeals has stated:

"Practical utility is a shorthand way of attributing "real-world" value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." A 'use' to do further research is not considered a utility which provides an "immediate benefit" to the public.

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Examples of situations requiring further research to identify or reasonably confirm a "real world" context of use, and which do not have utility under 35 USC 101, as set forth in MPEP 2107.01.1, include:

(A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved, and

(C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility.

The result of practicing the claimed invention is the determination of a naturally occurring correlation between an unspecified locus in an unspecified genome of a first unspecified species to an unspecified trait associated in a second unspecified species. As such the instant claims encompass a process of basic research that involves the study of naturally occurring correlations between non-specific genetic sequences and non-specific traits in population of a non-specific species. As noted in the utility guidelines (see Federal Register, December 21, 1999, Vol. 64, No. 244), basic research on a product to identify properties is an insubstantial utility (see page 6 of the Utility guideline training materials). For these reasons the instant claims lack a substantial utility as they are drawn only identifying nonspecific, naturally occurring properties and mechanisms. Further, applicants argument that one of skill in the art would recognize what these results mean (and thus how it can be used) amounts to an unsupported assertion that any correlation established between any genetic locus causally linked to any exhibited trait of a first, non-specific species and another genetic locus causally linked to any trait of a second non-specific species is always useful. Contrary to applicants arguments, there is no evidence of record that would support applicants assertion. The examiner maintains that further research would be required in order to determine what substantial utility an identified correlation would actually have, if any,

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when the instant claims only involve characterizing non-specific genes, non-specific species, and non-specific traits.

For the benefit of applicants, the examiner would like to strongly encourage applicants and/or their legal representatives to contact the examiner in order to conduct an interview (either telephonic or in-person) in order to discuss the basis of the current rejections of record. The examiner believes that such an interview would facilitate examination in this application by discussing potential amendments to the instant claims that may overcome the current rejections of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 168-194 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is newly applied and necessitated by applicants amendments to the instant claims.

Independent claims 168, 178, and 188 have been amended to recite that a suitably programmed computer performs at least one of the recited process steps set forth in said independent claims. This causes the metes and bounds of the instant claim to be indefinite because it cannot be determined what specific steps and operations the recited suitably programmed computer actually performs with regard to the recited steps

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of identifying a gene, mapping a gene, and determining whether or not naturally occurring correlations exist between generic genetic loci of a segregated population. The indefiniteness issue is further compounded by the recitation of the suitably programmed computer performs “at least one” of the recited process steps. The scope of the newly recited limitation encompasses those embodiments wherein all process steps are to be performed by said suitably programmed computer. This raises an indefiniteness issue with regard to the metes and bounds of the instant claims because the recited process steps involving identifying genes in a segregated population is generally accomplished by means of physical experimentation. Absent a recitation of the specific acts and/or computations involving a suitably programmed computer, it cannot be determined from the instant claims how a suitably programmed computer alone can carry out the physical experimentation required in order to establish (identify) genes that are causal for an exhibited trait as instantly claimed. It is unclear from the instant claims what physical experimental acts are encompassed and excluded from the instant claims as well as what specific series of acts or computations the suitably programmed computer are required in order to practice the claimed invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. DEJONG whose telephone number is (571)272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ERIC S. DEJONG/

Primary Examiner, Art Unit 1631